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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/757,788 | 01/10/2001 | Keith Anderson | 6116.200-US | 8259 |

7590 08/13/2003

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EXAMINER

TELLER, ROY R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1654 | |

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/757,788 | ANDERSON ET AL. | |
| | Examiner Roy Teller | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 June 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to Paper No: 18, in which applicant elected group I, claims 1-8 without traverse. Applicant further elected the following species without traverse: Arg-34-GLP-1(7-37)-OH, spacer gamma Glu, and Arg34Lys26(N-gamma-gluamyl(N-hexadecanoyl))-GLP-1(7-37)-OH.

Claims 1-8 are pending.

Information Disclosure Statement

The information disclosure statement filed 5/7/01 (Paper No: 5) is acknowledged. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “optionally”, it is unclear whether the lipophilic substituent is necessary for the operation of the invention.

Claims 2-8 are included in this rejection for depending upon a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermeling, USPN 6,380,357.

The instant invention is drawn to a pulmonary liquid or dry formulation comprising a GLP-1 compound, SEQ ID NO:1, wherein a lipophilic substituent is optionally attached via a spacer.

Hermeling teaches crystals of glucagon-like peptide-1 related molecules that are useful for treating diabetes, obesity and related conditions, see abstract. Hermeling describes SEQ ID NO: 20 (column 25) which is a 45% query match with SEQ ID NO:1 of the instant application, see GenCore version 5.1.6, page 1, result 1. Hermeling teaches the crystals can be formulated for parenteral administration, see column 6, lines 61-62. In Taber's cyclopedic medical dictionary, 15th edition, parenteral is defined as any route other than the alimentary canal, such as mucosal, see page 1234. Further, in Taber's cyclopedic medical dictionary, under medication route, the mucosal routes of administration include absorption through the nasal mucosa, buccal mucosa or

Art Unit: 1654

the bronchioles, the latter usually achieved through inhalation of an aerosol, see page 1018.

Absent evidence to the contrary, the glucagons-like peptide-1 crystals of Hermeling would be useful for pulmonary administration.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the crystals of glucagon-like peptide-1 related molecules of Hermeling, because Hermeling teaches the use of the crystals of glucagon-like peptide-1 related molecules for treating diabetes, obesity and related conditions.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Art Unit: 1654

RT

1654

8/12/03

RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER